Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D0874614	11/13/2024
Name of Provider or Supplier	**Street Address, City, State**	
Lab Clin Borinquen San Francisco	Centro Comercial San Francisco Ave De Diego 201, San Juan, PR	

For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D0000	The Centers for Medicare & Medicaid Services (CMS) conducted an unannounced CLIA recertification survey at LABORATORIO CLINICO BORINQUEN SAN FRANCISCO on November 13, 2024. The laboratory was surveyed under 42 CFR part 493 CLIA requirements. The following standard level deficiencies were found during the unannounced routine CLIA recertification survey ending on November 13, 2024.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on laboratory competence schedule, personnel file review (years 2023-2024) and laboratory general supervisor interview on November 13, 2024 at 9:00 AM, it was determined that the laboratory failed to follow the established schedule for the general supervisor competence as testing personnel since January 2023. The findings include: 1. On November 13, 2024 at 9:00 AM the competence schedule was reviewed. The schedule showed that the testing personnel competence must be performed every year. 2. On November 13, 2024 at 9:10 AM the laboratory general supervisor confirmed that the general supervisor competence as testing personnel was not performed since January 2023..
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test

	procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: A. Based on hematology procedure manual, calibration records (years 2023-2024) and laboratory general supervisor interview on November 13, 2024 at 11:00 AM, it was determined that the laboratory did not include, in their procedure manual, written procedures for calibration adjustments. The findings include: 1. The laboratory uses Beckman Coulter DxH690T hematology system to perform Complete blood count (CBC) patient's samples tests. Reviewed at 11:00 AM 2. Review of records showed that the laboratory performed calibration procedures twice a year. Reviewed at 11:05 AM 3. The Beckman Coulter calibration record from July 17, 2024, showed that calibration adjustments were perform to Red blood cells (RBC) and White blood cells (WBC) calibration factors due failures. Reviewed at 11:10 AM 4. Review of the hematology procedure manual on November 13, 2024 at 11:15 AM, showed that the laboratory did not include any written procedure for calibration adjustments. B. Based on review of coagulation studies written procedures, control material manufacturer's insert and interview with the laboratory general supervisor on November 13, 2024 at 12:00 M, it was determined that the laboratory did not have written procedures to evaluate the unassayed control material acceptability criteria. 1. The laboratory uses the HemosIL control material (level 1 and 2) for the Prothromgin and Partial Prothrombin Time studies processed by ACL Elite Pro coagulation instrument. Reviewed at 12:05 PM 2. The manufacturer's insert showed that the control material was evaluated for the ACL Classic instrument not for the ACL Elite Pro. Reviewed at 12;10 PM 3. Review of the coagulation studies written procedures did not include instructions about how to establish the acceptability criteria for the unassayed control material. 4. The laboratory general supervisor confirmed on November 13, 2024 at 12: 30 PM that the procedure manual did not include procedures to establish the unassayed control acceptable range based on instrument and control material combination.
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for

	example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on coagulation studies quality control records (years 2023-2024), control material inserts and interview with the laboratory general supervisor on November 13, 2024 at 11:00 AM, it was found that the acceptability criteria of the coagulation control material, based on the established results of an assayed material. The control material used by the laboratory was not evaluated for the instrument used by the facility. The findings include: 1. The laboratory performs Prothombin time (PT) and Partial Prothombine time (PTT) sample patient's test by ACL Elite Pro coagulation system. 2. Review of the coagulation control records from August 2024 to October 2024, showed that the laboratory verified the control material acceptability criteria for lot #N0139009, in August 2024. 3. The manufacturer claimed a control range for PT level 1 was 10.0 - 13.0 seconds and PT level 2 was 17.0 - 23. 0 seconds 4. The laboratory established a PT control range for level 2 of 25.6 - 34.6 seconds. This range was outside the manufacturer's limits. 5. Review of the manufacturer's insert showed that the control material was evaluated for the ACL Classic not the ACL Elite Pro. 6. The supervisor was interviewed about the laboratory procedure to establish the acceptability and control range of the control material and confirmed that the laboratory used the validation data obtained to establish their control range, but the laboratory did not have written procedures for this. 5. The laboratory processed and performed 415 Prothombin time test (PT) sample test those days.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on procedure manuals, quality control records review (years 2023-2024) and laboratory general supervisor interview on November 13, 2024 at 12:30 PM it was determined that the director failed to written the established policies for the laboratory to use the validation data obtained to establish their control range to evaluate the analytic process. Refer to D5403.
D5891	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the postanalytic systems specified in 493.1291.

	This STANDARD is not met as evidenced by: Based on sperm count and morphology, sperm count & morphology final test report review and interview with the laboratory general supervisor interview on November 13, 2024 at 11:45 AM, it was determined that the laboratory did not assure that the correct sample collection date were included in the sperm count & morphology final test reports. The findings include: 1.The laboratory final test report included a space to document the sample collection time. 2. Review of the sperm count & morphology final test report showed that the sample collection time was different from the one included in the patient work sheet. 3. The laboratory general supervisor confirmed on November 13, 2024 at 11:50 AM, that the laboratory failed to include in the final collection time as the one recorded in the worksheets.
D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality control programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on hematology control records review and interview with the laboratory general supervisor on November 13, 2024 at 12:30 AM, it was determined that laboratory director failed to ensure compliance with the requirements for analytic systems. Refer to D5403 and D5469.
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on hematology control records review and interview with the laboratory general supervisor on November 13, 2024 at 12:30 AM, it was determined that laboratory failed to ensure compliance with quality assessment (QA) requirements. The findings include: 1. The director failed to written the established policies for the laboratory to use the validation data obtained to establish their control range to evaluate the analytic process. Refer to D5791. 2. The laboratory did not assure that the correct sample collection date were included in the sperm count & morphology final test reports. Refer to D5891.
D6103	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(13) The laboratory director must ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and

	proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills. This STANDARD is not met as evidenced by: Based on laboratory competence schedule, personnel file review (years 2023-2024) and laboratory general supervisor interview on November 13, 2024 at 9:00 AM, it was determined that the laboratory failed to ensure that a comprehensive mechanism is used to evaluate the competency of the general supervisor as testing personnel. The finding includes: 1. The laboratory testing personnel include on medical technologist and technical supervisor, technical consultant and general supervisor (MT#1). Reviewed on 9:00 AM 2. The testing personnel records for MT #1 showed on November 13, 2024 al 9:00 A.M that the laboratory did not include the following requirements in his competency evaluation performed since January 2023: a. Direct observations of routine patient test performance , including patient preparation, if applicable, specimen handling, processing and testing. b. Monitoring the recording and reporting of test results. c. Review of intermediate test results or worksheets, quality control records, proficiency testing record and preventive maintenance records. d. Direct observation of performance of instrument maintenance and function checks. e. Assessment of problem solving skills. Review at 9:10 AM. Refer to D5209.
D6144	GENERAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1463 The general supervisor is responsible for day-to-day supervision or oversight of the laboratory operation and personnel performing testing and reporting test results. This STANDARD is not met as evidenced by: Based on procedure manuals, quality control records review (year 2024) and laboratory general supervisor interview on November 13, 2024 at 12:30 PM, it was determined that the general supervisor did not assure that quality control procedures were followed by the testing personnel. Refer to D5403 and D5469.